

Biopure Corporation (ticker: BPUR, exchange: NASDAQ) News Release - 12/24/2003

Biopure Receives 'Wells Notice' From Securities and Exchange Commission

CAMBRIDGE, Mass., Dec. 24 /PRNewswire-FirstCall/ -- Biopure Corporation (Nasdaq: BPUR) reported that on December 22, 2003, it received a "Wells Notice" from the staff of the Securities and Exchange Commission (SEC) indicating the staff's preliminary decision to recommend that the SEC bring a civil injunctive proceeding against the company. As permitted under the Wells process, Biopure intends to respond promptly and thoroughly in writing before the SEC staff formally decides what action, if any, to recommend. The company's chief executive officer and its former senior vice president of Regulatory and Operations also received Wells Notices.

Biopure believes the notices relate to the company's disclosures concerning its communications with the Food and Drug Administration (FDA) about a trauma study protocol the company submitted to the Agency in March 2003 and about the company's biologics license application (BLA) for Hemopure(R) [hemoglobin glutamer - 250 (bovine)]. The company did not publicly disclose its communications with the FDA about the proposed trauma protocol and investigational new drug application (IND) because it does not believe communications about proposed clinical trials are material prior to the initiation of a trial. This trauma trial was not initiated in the United States and no product was shipped under this IND. Biopure also believes that its disclosures about the BLA are accurate. The company will continue to cooperate with the SEC staff.

Biopure submitted the trauma protocol for a Phase II clinical trial of Hemopure for the treatment of hemorrhagic shock casualties in the hospital setting, where red blood cell transfusions are available. The FDA placed this trauma protocol under a new IND that is separate from the company's previous IND and its BLA to market Hemopure for the treatment of acutely anemic adult patients undergoing orthopedic surgery and for the elimination or reduction of red blood cell transfusions in these patients. The protocol sought to administer up to 15 units of Hemopure, a proposed dosage that was 50 percent higher than administered in previous clinical trials.

After the in-hospital trauma protocol was submitted to the FDA and the new IND was assigned, the Agency placed a clinical hold on the proposed trauma trial due to safety concerns. The FDA referred to a review of adverse event data from the company's Phase III orthopedic surgery trial, which was submitted in the BLA. The data from that Phase III trial has been previously presented at medical meetings.

In May 2003, Biopure responded to the FDA's clinical hold and also filed the response as a BLA amendment because it discussed data previously submitted with the BLA. That amendment resulted in the FDA extending its BLA review period up to 90 days, as previously announced on May 30, 2003. The Agency also requested three additional pre-clinical animal studies of Hemopure in conscious swine to address its concerns regarding high-volume administration. After the company's responses, the FDA has twice declined to lift the clinical hold, most recently in a letter dated July 30, 2003. This letter is separate from the FDA complete response letter Biopure received on that date in response to its BLA for orthopedic surgery. The questions in the FDA's trauma letter were the same as some of the questions in the BLA complete response letter and had two additional questions, one about the company's analysis of age-specific effects in individuals over age 75 in the Phase III orthopedic surgery trial and a second question about dosing.

Biopure submitted a similar study protocol for in-hospital testing of Hemopure in trauma patients to the Medicines Control Council (MCC) in South Africa. The MCC approved the protocol after modifications including lowering the maximum dose of Hemopure. In addition, the company continues to work with its trauma advisors, including military and academic researchers, to develop a clinical trial protocol, with funding from the U.S. Department of Defense, to test Hemopure in trauma patients in an out-of-hospital setting where blood is not available. The company believes that the risk-benefit ratio is different in the out-of-hospital setting. The company has withdrawn the U.S. in-hospital trauma protocol that was on clinical hold while it continues to develop its trauma program.

A Biopure-requested meeting has been scheduled with the FDA on January 6, 2004, to discuss the BLA. If there are significant developments at or following this meeting, the company intends to report them promptly. Biopure still expects to respond to the questions in the FDA's complete response letter by June 30, 2004.

Biopure Corporation

Biopure Corporation, headquartered in Cambridge, Mass., develops, manufactures and markets oxygen therapeutics, a new class of pharmaceuticals that are intravenously administered to deliver oxygen to the body's tissues. Hemopure(R) [hemoglobin glutamer - 250 (bovine)], or HBOC-201, is an investigational product in North America and Europe and is approved in South Africa for the treatment of acutely anemic surgical patients and for the elimination, delay or reduction of red blood cell transfusions in these patients. In July 2003, the U.S. Food and Drug Administration (FDA) sent Biopure a complete response letter regarding the company's biologics license

application to market Hemopure in the United States for a similar indication in orthopedic surgery patients. Biopure is currently preparing a comprehensive written response to the FDA's questions. Oxyglobin(R) [hemoglobin glutamer - 200 (bovine)], or HBOC-301, is the only product of its kind approved by the FDA and the European Commission for the treatment of anemia in dogs.

Statements in this press release that are not strictly historical may be forward-looking statements. There can be no assurance that Biopure Corporation will be able to commercially develop its oxygen therapeutic products, that necessary regulatory approvals will be obtained, that anticipated milestones will be met in the expected timetable, that any clinical trials will be successful, or that any approved product will find market acceptance and be sold in the quantities anticipated. Actual results may differ from those projected in forward-looking statements due to risks and uncertainties that exist in the company's operations and business environment. These risks include, without limitation, the company's stage of product development, history of operating losses and accumulated deficits, and uncertainties and possible delays related to clinical trials, regulatory approvals, possible healthcare reform, manufacturing capacity, marketing, market acceptance, competition and the availability of sufficient financing to support operations. The company undertakes no obligation to release publicly the results of any revisions to these forward-looking statements to reflect events or circumstances arising after the date hereof. A full discussion of Biopure's operations and financial condition, and specific factors that could cause the company's actual performance to differ from current expectations, can be found on the company's Web site at www.biopure.com/corporate/legal/home_legal.htm and in the company's filings with the U.S. Securities and Exchange Commission, which can be accessed in the EDGAR database at the SEC Web site, www.sec.gov, or through the Investor section of Biopure's Web site, www.biopure.com.

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